REMARKS

Entry of the foregoing and reconsideration of the application identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.111 and in light of the remarks which follow, are respectfully requested.

By the above amendments, the specification at page 2 has been amended to correct a typographical error, and now correctly identifies the US-A-5,626,861 document. The abstract has been amended for readability purposes.

By the above amendments, claim 14 has been amended to recite the phrase "of the surface area" after "a major portion," in accordance with the Examiner's suggestion. Claim 26 has been amended to depend from claim 23. Claim 27 has been amended to correct typographical errors, and now recites "about 0.1 μm to about 6 μm." Support for this amendment can be found in the instant specification at least at page 13, lines 18-20. Claims 14, 16, 23, 32, 33 and 35-37 have been amended for readability and/or clarification purposes.

The specification and abstract stand objected to for the reasons discussed at page 3 of the Official Action. These objections are moot in light of the above amendments, in which the specification and abstract have been amended in accordance with the Examiner's suggestions. Accordingly, withdrawal of the objections is respectfully requested.

Claims 27-29, 32 and 35 stand objected to under 37 C.F.R. §1.75(c), for the reasons discussed at pages 3-4 of the Official Action. This objection is moot in light of the above amendments, in which claim 27 has been amended to recite a range of about 0.1 μm to about 6 μm. Moreover, it is noted that claim 26, from which claim 27 depends, has been amended to depend from claim 23. Further, claims 32 and 35 have been amended in accordance with the Examiner's suggestions. Accordingly, withdrawal of the above claim objection is respectfully requested.

Claims 14-43 stand rejected under 35 U.S.C. §112, second paragraph, for the reasons set forth at pages 4-5 of the Official Action. Without addressing the propriety of the Examiner's comments, and in an effort to expedite prosecution, claim 14 has been amended to recite the phrase "of the surface area", in accordance with the Examiner suggestion.

With regard to claim 18, Applicants submit that the term "regular" refers to a structure of uniform shape, such as a spherical shape as discussed at page 7, lines 8-12 of the instant specification. Concerning claim 26, it is noted that such claim has been amended to depend from claim 23, which provides antecedent basis for the term "hollow granules."

With regard to the Examiner's comments concerning claim 28, Applicants respectfully note that in an exemplary embodiment, the granules can have both micropores and macropores. See, e.g., the specification.at page 6, lines 9-17.

For at least the above reasons, Applicants submit that the claims are in full compliance with the second paragraph of 35 U.S.C. §112. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 14-18, 20-25, 28-30, 32, 33 and 41-43 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,338,772 (*Bauer et al*) in view of U.S. Patent Application Publication No. US 2002/0016636 (*Ricci et al*). Claim 19 stands rejected under 35 U.S.C. §103(a) as being obvious over *Bauer et al* in view of *Ricci et al* and further in view of U.S. Patent No. 4,429,691 (*Niwa et al*). Withdrawal of these rejections is respectfully requested for at least the following reasons.

Independent claim 14 is directed to a biocompatible and biodegradable implant for filling a cavity in a living organism comprising polymer-coated biocompatible and biodegradable granules fused together through polymer linkage, said granules being made of biocompatible and biodegradable materials selected from the group consisting of

biopolymers, bioglasses, bioceramics and a mixture thereof, and said granules having an equivalent-diameter in a range from about 350 μm to about 2000 μm; a major portion of the surface area of said granules being coated with at least one biocompatible and biodegradable layer of a polymer selected from the group consisting of poly(α-hydroxyesters), poly(ortho esters), polyanhydrides, poly(phosphazenes), poly(propylene fumarate), poly(ester amides), poly(ethylene fumarate), polylactide, polyglycolide, polycaprolactone, poly(glycolide-co-trimethylene carbonate), polydioxanone, co-polymers thereof and a blend of those polymers and said polymer layer having a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of said implant.

Bauer et al does not disclose or suggest each feature recited in independent claim 14. For example, *Bauer et al* does not disclose or suggest a major portion of the surface area of said granules being coated with at least one biocompatible and biodegradable layer of a polymer, as recited in claim 14. By comparison, *Bauer et al* discloses the following at column 5, lines 19-25:

> A **decisive feature** of the composite material according to the invention is the three-dimensionally open-pore structure, which is constructed such that the calcium phosphate ceramic particles are joined to one another by polymer bridges, **the particle surfaces being covered with polymer to the extent of not more than 50%**. [Emphases added.]

Bauer et al teaches that not more than 50% of the particle surfaces are covered with polymer. This is in stark contrast with the claimed granules, for example, wherein **a major portion of the surface area of said granules** is coated with at least one biocompatible and biodegradable layer of a polymer. Clearly, in view of *Bauer et al*'s teaching of particle surfaces covered with polymer to the extent of not more than 50% for attaining a decisive feature of the material described therein, it would not have been obvious to modify *Bauer et*

al to employ a major portion of the surface area of said granules coated with at least one biocompatible and biodegradable layer of a polymer.

Furthermore, *Bauer et al* does not disclose or suggest that the polymer layer has a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of said implant, as recited in claim 14. Such deficiencies have been acknowledged by the Patent Office at page 6 of the Official Action.

Ricci et al and *Niwa et al* fail to cure the above-described deficiencies of *Bauer et al*. As discussed above, *Bauer et al* teaches employing not more than 50% coverage of the particle surfaces to attain a decisive feature of the composite material described therein. Col. 5, lines 19-25. The Patent Office has relied on *Ricci et al* for disclosing, *inter alia*, specific thicknesses and amounts of a polymer coating, and *Niwa et al* has been relied on for disclosing the use of spherical shaped calcium phosphate granules. Official Action at pages 6 and 10. However, such secondary applied documents would not have rendered it obvious to modify *Bauer et al* to arrive at a major portion of the surface area of said granules coated with at least one biocompatible and biodegradable layer of a polymer, in view of *Bauer et al*'s teachings of the importance of employing not more than 50% coverage of the particle surfaces.

Furthermore, Applicants respectfully traverse the Examiner's assertion that it would have been obvious to modify *Bauer et al* in view of *Ricci et al*'s disclosure of the use of a specific thickness and amount of a polymer coating, in order to control the resorption rate of the implant composition. Official Action at page 6. As noted by the Examiner, the polymer disclosed by *Ricci et al* is used for the purpose of controlling the resorption rate of the implant composition and as such, the specific thicknesses and amounts disclosed by *Ricci et al* are for obtaining such resorption rate characteristics. This function, however, is

completely different from that of the polymer bridges disclosed by *Bauer et al*, which have the purpose of joining calcium phosphate particles to one another. Col. 5, lines 19-25. Clearly, in light of such stark functional differences, it would not have been obvious to employ the polymer thicknesses and amounts disclosed by *Ricci et al* in the *Bauer et al* polymer bridges.

Dependent claim 18 is further distinguishable from the above applied art. The applied art simply has no disclosure or suggestion of granules of a regular shape, as recited in such claim. Applicants submit that in view of the fact that the shape of granules can widely vary and not all granules are of a regular shape, the Patent Office has not met its burden of showing with the **requisite certainty**, that the applied art inherently discloses granules of a regular shape.

For at least the above reasons, the claims are not obvious over *Bauer et al*, *Ricci et al* and *Niwa et al*. Accordingly, withdrawal of the above rejections is respectfully requested.

Claims 14-25, 28-30 and 32-37 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,648,097 (*Nuwayser*), in view of *Bauer et al* and further in view of *Ricci et al*. Claims 26 and 27 stand rejected under 35 U.S.C. §103(a) as being obvious over *Nuwayser* in view of *Bauer et al* and further in view of *Ricci et al* and U.S. Patent No. 6,455,024 (*Glajch et al*). Claim 31 stands rejected under 35 U.S.C. §103(a) as being obvious over *Nuwayser* in view of *Bauer et al* and further in view of *Ricci et al* and U.S. Patent No. 4,610,692 (*Eitenmuller et al*). Claims 38-40 stand rejected under 35 U.S.C. §103(a) as being obvious over *Nuwayser* in view of *Bauer et al* and further in view of *Ricci et al* and International Publication No. WO 00/50104 (*Ruffieux et al*). Withdrawal of these rejections is respectfully requested for at least the following reasons.

Nuwayser does not disclose or suggest each feature recited in independent claim 1. For example, as acknowledged by the Patent Office at page 11 of the Official Action, *Nuwayser* does not disclose or suggest granules having an equivalent-diameter in a range from about 350 μm to about 2000 μm, and that said polymer layer has a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of the said implant.

Applicants note that by employing the equivalent-diameter range and the polymer layer thickness and weight fraction ranges in accordance with an exemplary aspect, an implant can be obtained, for example, having an open interconnected macro porosity which can in turn advantageously allow for tissue in-growth. Specification at page 5, lines 11-12. *Nuwayser* and the secondary applied documents fail to provide any recognition or suggestion of the result-effective nature of the equivalent-diameter range and the polymer layer thickness and weight fraction ranges upon obtaining open interconnected macro porosity and promoting tissue in-growth. Accordingly, for at least this reason, it would not have been obvious to combine the applied documents and optimize ranges disclosed therein to arrive at the claimed equivalent-diameter range and polymer layer thickness and weight fraction ranges.

Furthermore, it is respectfully noted that, whereas *Bauer et al* relates to the use of polymer bridges for joining calcium phosphate ceramic particles to one another, *Nuwayser* is concerned with obtaining mineral microparticles having characteristics useful for bioerodible delivery systems. *Bauer et al* at col. 5, lines 19-25; *Nuwayser* at col. 4, lines 25-34. In view of such differences in function, it would not have been obvious to modify *Nuwayser* to employ the particle size range disclosed by *Bauer et al* as proposed by the Patent Office.

As discussed above, the other applied art (i.e., *Ricci et al*, *Glajch et al*, *Eitenmuller et al* and *Ruffieux et al*) fails to cure the above-described deficiencies of *Nuwayser*. Simply put, it would not have been obvious in view of such documents, to arrive at the claimed granules having an equivalent-diameter in a range from about 350 μm to about 2000 μm, and a polymer layer having a thickness in a range of 2 μm to 300 μm corresponding to a weight fraction of about 4% to about 15% of the weight of the said implant.

For at least the above reasons, withdrawal of the §103(a) rejections is respectfully requested.

Claim 14 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 36, 42 and 43 of copending Application No. 10/540,323. The Examiner is respectfully requested to hold this rejection in abeyance until the present application is deemed to otherwise be in condition for allowance.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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